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CELERA			SHAW, AMANDA MARIE	
ATTN: Victor Lee, Vice President			ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)
	10/796,307	CARGILL ET AL.
	Examiner	Art Unit
	Amanda M. Shaw	1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 04 May 2007.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-4, 6, 21 and 22 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-4, 6, 21, and 22 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____	6) <input type="checkbox"/> Other: _____

DETAILED ACTION

1. This action is in response to the amendment filed May 4, 2007. Applicant's arguments have been fully considered but are not persuasive to overcome all grounds of rejection. All rejections not reiterated herein are hereby withdrawn. This action is made FINAL.

Claims 1-4, 6, and 21-22 are currently pending. Claims 1 and 21 have been amended. Therefore Claims 1-4, 6, and 21-22 will be addressed herein.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on April 1, 2005 has been considered as indicated in the previous Office Action. It was brought to the examiners attention that one of the references on the IDS was not considered when it should have been. As a result the examiner is sending out an additional IDS form in which the reference has been considered. Please note that references which have lines drawn through them have been considered as indicated on the IDS form mailed with the Office Action of November 6, 2006.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 6, and 21-22 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the reasons set forth in the Office Action of November 6, 2006 and reiterated below.

The claims are broadly drawn to a method for identifying an individual who has an altered risk for developing myocardial infarction comprising detecting any single nucleotide polymorphism in SEQ ID NO: 33944. The specification teaches that SEQ ID NO: 33944 is 201 base pairs in length. The specification teaches a single C/T polymorphism at position 101 of SEQ ID NO: 33944. However the claims encompass any SNP in SEQ ID NO: 33944. However the specification does not disclose and fully characterize a sufficient number of SNPs that are representative of the genus required by the claims of any SNP in SEQ ID NO: 33944.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2b 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed". Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. In The Regents of the University of California v. Eli Lilly (43 USPQ2b 1398-1412), the court held that a generic statement which defines a genus of

Art Unit: 1634

nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA..." required a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention".

In analyzing whether the written description requirement is met for a genus claim, it is first determined whether a representative number of species have been described by their complete structure. In the instant case, only one SNP in SEQ ID NO: 33944 has been identified. No additional nucleotide variations have been disclosed in the specification. Therefore the specification does not teach the complete structure of a representative number of species of the claimed genus. It is then determined whether a representative number of species have been sufficiently described by other relevant identifying characteristics (e.g. restriction map, biological activity of an encoded protein product, etc.). In the instant case, no such identifying characteristics have been provided. Yet, the claims as written are inclusive of a potentially large genus of SNPs in SEQ ID NO: 33944. While one could contemplate a nucleotide substitution, deletion or addition at each and every position in SEQ ID NO: 33944, such nucleotide variations are not considered to be equivalent to specific nucleotide variations associated with myocardial infarctions. Rather, the mutations in SEQ ID NO: 33944 that are associated

with myocardial infarctions represent a distinct group of nucleotide variations which are expected to occur at only specific locations within SEQ ID NO: 33944 and consist of specific nucleotide alterations. Accordingly, knowledge of the sequence of the wild-type gene does not allow the skilled artisan to envision all of the contemplated polymorphisms encompassed by the claimed genus. Conception of the claimed invention cannot be achieved until reduction to practice has occurred, regardless of the complexity or simplicity of potential methods for isolating additional nucleotide variations. As stated in *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. LTD*, 25 USPQ2d 1016, one cannot describe what one has not conceived.

For these reasons, Applicants have not provided sufficient evidence that they were in possession, at the time of filing, of the invention as it is broadly claimed and thus the written description requirement has not been satisfied for the claims as they are broadly written. Applicants attention is drawn to the Guidelines for the Examination of Patent Applications under 35 U.S.C. 112, ¶ 1 'Written Description' Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Response To Arguments

4. In the response filed May 4, 2007, Applicants amended to the claims to overcome the written description requirement. Specifically claims 1 and 21 were amended to recite one SNP as represented by SEQ ID NO: 33994. This amendment has been fully considered but is insufficient to over come the written description

Art Unit: 1634

rejection. Once again it is noted that SEQ ID NO: 33944 is 201 base pairs in length and the specification teaches a single C/T polymorphism at position 101 of SEQ ID NO: 33944. However since the claims do not recite the specific position of the SNP within SEQ ID NO 33944, the claims encompass detecting a SNP at any nucleotide position of SEQ ID NO: 33994. Additionally the claims lack written description because they do not recite the specific wild type and/or polymorphic allele at position 101 of SEQ ID NO: 33944. Therefore the claims encompass detecting any allele (i.e., A, T, G or C) at position 101 of SEQ ID NO: 33994.

5. Claims 1-4, 6, and 21-22 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for identifying an individual who has an increased risk for developing myocardial infarction, comprising detecting the presence of single nucleotide polymorphism at position 101 of SEQ ID NO 33944 wherein the detection of the SNP is correlated with an altered risk for myocardial infarction, does not reasonably provide enablement for methods for identifying an individual who has an altered risk for developing myocardial infarction, comprising detecting the presence of single nucleotide polymorphism at any position of SEQ ID NO 33944 wherein the detection of the SNP is correlated with an altered risk for myocardial infarction. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The following factors have been considered in formulating this rejection (*In re Wands*, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988): the breadth of the claims, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, the amount of direction or guidance presented, the presence or absence of working examples of the invention and the quantity of experimentation necessary.

Breadth of the Claims:

The claims are drawn broadly to a method for identifying an individual who has an altered risk for developing myocardial infarction, comprising detecting a single nucleotide polymorphism in SEQ ID NO: 33944. Thus the claims encompass methods which detect any nucleotide variation within SEQ ID NO: 33944. The claims do not define the identity or position of any nucleotide variation within SEQ ID NO: 33944. Claim 2 further states that the SNP is associated with an increased risk for developing myocardial infarction while claim 4 further states that the SNP is associated with a decreased risk for developing myocardial infarction. Claim 3 requires that the individual has previously had a myocardial infarction. Claims 6 and 21-22 deal with methods for detecting the SNP.

Nature of the Invention

The claims are drawn broadly to a method for identifying an individual who has an altered risk for developing myocardial infarction, comprising detecting a single nucleotide polymorphism in SEQ ID NO: 33944. The invention is in a class of inventions which the CAFC has characterized as 'the unpredictable arts such as

chemistry and biology" (Mycogen Plant Sci., Inc. v. Monsanto Co., 243 F.3d 1316, 1330 (Federal Circuit 2001)).

Teachings in the Specification and State of the Art:

The specification teaches a single C/T mutation at nucleotide position 101 of SEQ ID No 33944. The specification teaches that this mutation is a missense mutation and that it is associated with the occurrence of myocardial infarctions. It is further noted that this particular SNP is referenced as rs6685323 and hCV25753038 throughout the specification. The NCBI website teaches that rs6685323 is located on chromosome 1 within the AQP10 gene.

The specification further teaches on page 120 that to identify markers associated with myocardial infarction two case control studies were performed. One study had 1400 samples in which patients had self-reported history of myocardial infarction and the controls had no history of myocardial infarction. The second study had 1500 samples in which patients had clinical evidence of history of myocardial infarction and controls had had no history of myocardial infarction. Allele specific PCR was used to determine the allele frequencies of the SNPs. The results are shown in Table 6. Specifically for SNP hCV25753038 the odds ratio was 1.2 for the first study and 1.3 for the second study.

The specification also teaches on page 121 that to identify markers associated with recurrent myocardial infarction samples from the Cholesterol and Recurrent Events cohort were genotyped. A well-documented myocardial infarction was a requirement to be part of the cohort. The SNP genotype frequencies of a group of 264 patients who

Art Unit: 1634

had recurrent myocardial infarctions were compared to the SNP genotype frequencies to a group of 1255 patients who had only one myocardial infarction. The results are shown in Tables 7-8. There is no specific data provided for SNP hCV25753038.

The specification and prior art do not teach any other variations in the AQP10 gene or SEQ ID NO: 33944 that are associated with myocardial infarction. The specification further does not teach that the mutation at position 101 of SEQ ID NO: 33944 is associated with myocardial infarction in any other organisms other than humans. Additionally there are no teachings in the specification in which the mutation at position 101 of SEQ ID NO: 33944 is associated with recurrent myocardial infarctions.

The Predictability or Unpredictability of the Art and Degree of Experimentation:

The art of identifying novel variants in any nucleic acid sequence which are sufficiently correlated with a disease or condition that further allow for identifying an individual who has an altered risk for developing a disease or condition is highly unpredictable. Knowledge of any wild type sequence does not allow one to immediately envision any mutation in that sequence that is associated with a specific disease or condition.

The AQP10 gene is expected to contain numerous polymorphisms, particularly given the size of the gene. Thus SEQ ID NO: 33944 is also expected to contain numerous polymorphisms. However, the specification does not teach a predictable means for identifying additional variations associated with myocardial infarctions or for distinguishing between variations associated with myocardial infarctions and naturally occurring polymorphisms. Without extensive information regarding the structure-function

Art Unit: 1634

relationship between the AQP10 gene and myocardial infarctions, it is highly unpredictable as to what would be the identity of additional mutant, allelic, or splice variants which would be associated with myocardial infarctions. Thus, one cannot readily anticipate the effect of a polymorphism or mutation on the function or activity of the AQP10 gene or the protein encoded thereby.

Further, it is unpredictable as to whether the results obtained in human subjects could be extrapolated to other organisms. Knowledge that mutations in a gene occur in one organism (i.e. humans) does not allow one to conclude that this gene, and mutations in this gene will also occur in other organisms and will be associated with myocardial infarctions. The specification does not teach homologues of the AQP10 gene in a representative number of different organisms. The specification also does not teach any other organisms which have myocardial infarctions, such that one would expect that mutations in the homologous AQP10 genes would lead to myocardial infarctions in other organisms. This is supported by the findings of Morinaga et al (Biochemical and Biophysical Research Communication 2002) that teach that the AQP10 gene in mice is a pseudogene. Morinaga also teach that the exons of the AQP10 gene are well conserved between mouse and human but the initiator methionine is lost in mice due to a mutation at the translation initiation site. Thus it is unpredictable as to whether the AQP10 gene, and particularly the mutation at position 101 of SEQ ID No: 33944 will also be present in other organisms and will be associated with myocardial infarctions.

It is also unpredictable as to whether the SNP at position 101 of SEQ ID NO 33944 can be used to determine ones risk of having recurrent myocardial infarctions. Just because this mutation is found in people who have had one myocardial infarction it does not mean that it can be used as an indicator for recurrent myocardial infarctions. The data in the specification is limited to an association between this mutation and the risk of developing a single myocardial infarction. There are no teachings in the specification regarding an association between this mutation and multiple myocardial infarctions.

Amount of Direction or Guidance Provided by the Specification:

The specification teaches 1 variant of SEQ ID NO 33944 which is associated with myocardial infarctions. However, the SEQ ID NO 33944 is 201 base pairs long. To identify additional variants of SEQ ID NO 33944 which are associated with myocardial infarctions would require extensive experimentation. For example, such experimentation may involve sequencing the AQP10 gene of individuals who have had myocardial infarctions, sequencing the AQP10 gene of control individuals which have not had myocardial infarctions, comparing the sequences of these two groups, and then identifying variations which are present only in the affected group and not in the control group. Such random, trial by error experimentation is considered to be undue. While methods for sequencing genes are known in the art, such methods provide only the general guidelines that allow researchers to randomly search for mutations that may linked to a disease. The results of performing such methodology are highly unpredictable. The specification has provided only an invitation to experiment. The

Art Unit: 1634

specification does not provide a predictable means for identifying additional variants of SEQ ID NO 33944 and using these variants to identify individuals susceptible to myocardial infarctions.

Working Examples:

Again, the specification teaches on page 120 that to identify markers associated with myocardial infarction two case control studies were performed. One study had 1400 samples in which patients had self-reported history of myocardial infarction and the controls had no history of myocardial infarction. The second study had 1500 samples in which patients had clinical evidence of history of myocardial infarction and controls had had no history of myocardial infarction. Allele specific PCR was used to determine the allele frequencies of the SNPs. Specifically the applicants looked at the SNP at position 101 of SEQ ID NO 33994 and determined that it was associated with myocardial infarction. However there are no specific examples provided in the specification in which a subject is identified as being at risk of having a myocardial infarction by detecting any other variants of SEQ ID NO 33994. There are also no specific examples provided in the specification in which a subject is identified as being at risk of having recurrent myocardial infarctions by detecting the SNP at position 101 or any other variant of SEQ ID NO: 33994. Further, there are no working examples provided in the specification in which non-human subjects used.

Conclusions:

Case law has established that '(t)o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed

invention without 'undue experimentation.'" *In re Wright* 990 F.2d 1557, 1561. *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) it was determined that '(t)he scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art". The amount of guidance needed to enable the invention is related to the amount of knowledge in the art as well as the predictability in the art. Furthermore, the Court in *Genetech Inc. v Novo Nordisk* 42 USPQ2d 1001 held that '(I)t is the specification, not the knowledge of one skilled in the art that must supply the novel aspects of the invention in order to constitute adequate enablement".

In the instant case, the claims do not bear a reasonable correlation to the scope of enablement because the specification only teaches 1 mutation in SEQ ID NO: 33944 that is associated with myocardial infarctions. The specification does not teach a representative number of additional variants, including insertions, deletions, substitutions or splice variants, or gross chromosomal rearrangements which are associated with myocardial infarctions. Further, the specification does not teach how to use the mutation at position 101 of SEQ ID NO: 33944 as a means for predicting ones risk of having recurrent myocardial infarctions. Additionally, the disclosure of a single organism, humans, in which the mutation at position 101 of SEQ ID NO: 33944 is correlated with myocardial infarctions is not representative of the broadly claimed genus of any individual. Accordingly, although the level of skill in the art of molecular biology is high, given the lack of disclosure in the specification and in the prior art and the

unpredictability of the art, it would require undue experimentation for one of skill in the art to make and use the invention as broadly claimed.

Response To Arguments

6. In the response filed May 4, 2007, Applicants amended to the claims to overcome the enablement requirement. Specifically claims 1 and 21 were amended to recite one SNP as represented by SEQ ID NO: 33944. This amendment has been fully considered but is insufficient to over come the enablement. Claims 1-4, and 6 are still not enabled because the claims are drawn to a method for identifying a human who has an altered risk for developing myocardial infarction by detecting a SNP. First of all claim 1 does not state whether the altered risk is an increased or a decreased risk. Claim 1 further requires "detecting a SNP as represented by the nucleotide sequence of SEQ ID NO 33944". This phrase is not enabled because it is unclear if any polymorphic allele within SEQ ID NO: 33944 is associated with altered risk of myocardial infarction or if only a certain polymorphic allele (i.e., A, C, G, or T) at position 101 of SEQ ID No: 33944 is associated with altered risk of myocardial infarction. Further it is unclear which alleles at position 101 are associated with increased risk and which alleles are associated with decreased risk. Additionally claim 3 is not enabled because it is drawn to a method for identifying a human who has an altered risk for developing a recurrent myocardial infarction since claim 3 requires that the individual has previously had a myocardial infarction. While the specification teaches an association between the polymorphism at position 101 of SEQ ID NO 33944 and the risk of developing a

Art Unit: 1634

myocardial infarction, there are no teachings in the specification regarding an association between this mutation and multiple myocardial infarctions. Claims 21 and 22 are still not enabled because the claims are drawn to detecting a SNP by contacting a sample with a reagent that specifically hybridizes to the SNP as represented by the nucleotide sequence of SEQ ID NO 33944. This method is not enabled because it is unclear if the reagent specifically hybridizes to the SNP at position 101 of SEQ ID NO 33944 or if it can hybridize to any SNP within SEQ ID NO 33994. For these reasons the enablement rejection is maintained.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4, and 6 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the reasons set forth in the Office Action of November 6, 2007 and reiterated below.

Claims 1-4 and 6 are indefinite over the recitation of the phrase "wherein the presence of the SNP is correlated with an altered risk for myocardial infarction." Because the term "correlated" has not been clearly defined in the specification and because there is no art recognized definition for this term as it relates to a SNP and a disease, one of skill in the art cannot determine the meets and bounds of the claimed subject matter. Additionally the phrase "altered risk" encompasses an increased risk and a decreased risk. It is not clear as to how both an increase as a well as a decrease are risks for myocardial infarction.

Response To Arguments

8. In the response filed May 4, 2007, Applicants traversed the rejection over the phrase "correlated" by stating that the term has been clearly defined as to indicate a relationship between the presence of a particular SNP and the level of risk for developing myocardial infarction. Additionally applicants traversed the rejection over the phrase "altered risk" by stating that the Applicants invention teaches that there are two alleles at the designated SNP location, one of which causes increased risk, and one of which causes decreased risk. These arguments have been fully considered but are not persuasive to over come the rejections. While the specification teaches that individuals with a C at position 101 of SEQ ID NO 33994 are at a higher risk of myocardial infarction compared to individuals with a T at position 101 of SEQ ID NO 33944, the claims do not recite how the SNP is correlated with altered risk.

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

Art Unit: 1634

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda M. Shaw whose telephone number is (571) 272-8668. The examiner can normally be reached on Mon-Fri 7:30 TO 4:30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached at 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Amanda M. Shaw
Examiner
Art Unit 1634



DIANA JOHANNSEN
PRIMARY EXAMINER